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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,937	10/13/2004	Hubert Thoma	H-32407A	6977

74479 7590 04/16/2008

Novartis Animal Health US Inc.
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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,937	THOMA ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,22,24-30,32 -36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21,22,24-30,32 -36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There appears to be a typographical error, as the diameter can not be both 0.09 & 0.8.

Claim Rejections - 35 USC § 103

Claims21-22, 24-30, 32-36 stand rejected under 35 U.S.C. 103(a) as being unpatentable over PATEL et al W00137808 in view of FRIEDMAN –3824233 or MALNOE et al W002/071874 or ALFORD 3937825 or Thombre er al US 20030190343A1.

Patel, of record, provides animal, mammalian medicines (page 6, lines 14-17; page 7, line 2) encapsulated (page 6, line 2); including benazepril (page 7, line 4). The carrier is a starch sugar (page 51, line 29). The size is not defined, but it is inclusive of the instant, as nanosized and micronized powders are described (page 51) and 30-35 mesh (Example 1).

Processing of the coated carriers, with additive, inclusive of the instant feed, is described at page 52, bottom; page 53, top and includes pelleting and other art known processes; including tablets (page 59, line 19).

Preparation includes solvating the medicine to coat over the carrier (page 72 and 78, Example 1). Example 5 shows a typical animal feed- Mg carbonate. Also, such feeds are inclusive of additives are dicalcium, polyols, sugars, gelatin, zein, mussel protein, starch (page 58, lines 17-29).

Patel permits of all manner of inclusion of the additives-encapsulated with or separately from, the medicinal coated carrier, or mixed with the carrier (page 52, lines 20-25).

Given Patel, the artisan would have found it obvious to prepare the desired medicament for the particular animal patient, depending upon the syndrome to be treated, with additives of feed common to the animal species desired, and formulated as standard in the art as pellet or tablet. The carriers and protective agents shown by Patel are standard and known in the art. Patel's dosage forms are the applicants as claimed.

Patel's rationale for preparation, as applicant argues, is not applicant's. However, two different functions can be ascribed to the same dosage form, as is the case of the instantly claimed and Patel dosages.

ALFORD exemplifies the known combination coated sugars as carriers (column 2, bottom) for medicinals, further coated, as with shellac (column 3, line 16). The carriers/medicinal is mixed with animal feed, or prepared as a tablet or pellet with animal feed (column 2, lines 18-27).

Thrombe also provides tablets of animal (dog, cat) medicines, using a mix of medicine/carrier (example 1) with an animal feed. Feed provides palatability, & may be yeast @ 0.025-99% of the dosage form[0022.0055]. other feeds are herbs, milk, soy, starch, sugars & soy or cotton seed meal or oil[0045—48,0052]. Drugs include antimicrobials, antivirals, antiparasitics & neurotropics [0056]. However, the coatings are applied with drug, rather than over the drug coated carrier.

Given Patel's coating procedures, one of ordinary skill in the art would know the tablets could be prepared as of Thrombe, or coated with drug & then with a masking coating, as of Patel, & mixed with a feed selected to be palatable to the target animal patient.

The amounts and proportions of each ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each ingredient to optimize the effect desired, depending upon the particular species of interest.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that the arrangement of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

.Applicant's arguments filed 1/25/08 have been fully considered but they are not persuasive. Applicant argues no basis has been presented for the artisan to consider the combination of references cited. Given the recent 2007 supreme court decision in KSR V TELEFLEX @ 82 USPQ 2d @ 1385, examiner finds the artisan would have been aware of the various modes of tablet preparation, as the references indicate such procedures are art known &the Patel reference provides the instant compositions. The secondary references show it's known to select the tasty feed components, including yeast, to achieve tablet consumption by the target patient species.

/NEIL LEVY/

Primary Examiner, Art Unit 1615